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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,447	11/13/2003	Gattadahalli M. Anantharamiah	21085.0143U2	8707

23859 7590 06/13/2008

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EXAMINER	
KOLKER, DANIEL E	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
06/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,447	ANANTHARAMIAH ET AL.	
	Examiner	Art Unit	
	DANIEL KOLKER	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6 and 14-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6 and 14-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/17/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Sequence for GeneSeq ABG14272 (Drmanac et al), 1 page*.

DETAILED ACTION

1. The remarks and amendments filed 12 March 2008 have been entered. Claims 1 – 3, 5 – 6, and 14 – 17 are pending and under examination.

Withdrawn Rejections

2. The following rejections set forth in the previous office actions are withdrawn:

A. The rejections under 35 USC 112 second paragraph are withdrawn in light of the arguments and amendments. Applicant's arguments with respect to "capable of" are persuasive, given the arguments and the examples in the specification the term is not indefinite. Additionally, the amendment to claim 3 makes it clear that there is no upper limit on the length of the claimed polypeptide. The polypeptide may be at least 14, at least 15, at least 16, at least 17, or at least 18 amino acids long. A skilled artisan can determine the scope of claim 3.

B. The rejection under 35 USC 112, first paragraph, for lack of adequate written description is withdrawn in light of the arguments and upon further consideration. The specification sets forth several examples of polypeptides within the scope of the claims. Additionally, the newly revised written description guidelines, available on the internet at http://www.uspto.gov/web/menu/written.pdf , support applicant's arguments that the claimed invention has been described. Thus the rejection is withdrawn.

C. The rejection under 35 USC 112, first paragraph, for lack of enablement commensurate in scope with the claims, is withdrawn in light of the amendments. Claim 1 is now limited to polypeptides which bind lipoproteins.

New Rejections

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 6, 14 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drmanac (WO 01/75067) as evidenced by Alberts (1994. Molecular Biology of the Cell, 3rd Edition, p. 57) in view of Arlinghaus (U.S. Patent 6,107,457, issued 22 August 2000).

Drmanac teaches the polypeptide of SEQ ID NO:44631; see for example p. 2 lines 4 – 7, p. 4 lines 29 – 32. The protein is 142 amino acids long, the enclosed appendix shows the sequence near the bottom of the right-hand side of the page. Note residues 68 – 71 have the sequence GARRAGGTPPRAPR. Alberts p. 57 provides evidence that G, A, and P are all hydrophobic residues, note that the residues are referred to as non-polar, but that is a synonym for hydrophobic. This sequence therefore is within the scope of SEQ ID NO:210, as all the Arg residues are present, as are the X (Gly, Thr, Ser, Ala) and Y (hydrophobic) residues recited in the sequence. Drmanac teaches that the protein are to be synthesized, thus they are synthetic as recited in claim 1. While the reference is silent as to the ability of the peptide to form an amphipathic α helix and to bind lipoproteins, that is an inherent property of all proteins with this sequence. This point has been argued in detail by applicant, see for example declaration filed under 37 CFR 1.132 on 31 July 2007, particularly paragraph 6, as well as remarks filed 29 November 2006, p. 9 final paragraph where applicant states, in discussion of generic SEQ ID NO:210, that "each and every peptide encompassed by claim 1 is capable of forming an amphipathic α helical structure." Thus according to applicant, the protein sequence taught by Drmanac as SEQ ID NO:44631 necessarily has the appropriate properties. The protein comprises at least 14 amino acids, as recited in claim 3; it is 142 amino acids long. The protein can also be made recombinantly, as recited in claim 6; see p. 29 of Drmanac, third paragraph. Claims 14 – 15 are included in this rejection as they recite properties which applicant has indicated are necessarily provided for by the structure of SEQ ID NO:210. Finally, Drmanac teaches pharmaceutical compositions comprising the disclosed proteins; see for example the section beginning on p. 63 final paragraph. This is on point to claim 16, drawn to pharmaceutical compositions. See also Drmanac, p. 66 final paragraph which teaches both physiological saline and buffers are to be included in the formulation, and p. 70 first paragrpah

which discusses liposomes with multiple layers; these are on point to claim 17. Drmanac teaches that the protein is to be used to treat patients; see pp. 62 -63 for example. However Drmanac does not explicitly teach altering the protein by placing an acetyl group at the N terminus and an amide group at the C terminus, as recited in claim 1.

Arlinghaus teaches that an acetyl group can be added to the N-terminus of a protein or peptide sequence, and that an amide group can be added to the C-terminus. See paragraph spanning columns 7 – 8. Arlinghaus teaches that doing so protects the synthetic peptides from protease digestion that is known to occur within cells and organisms. This is on point to claim 1, specifically the limitation drawn to acetyl and amide groups. However Arlinghaus does not teach a protein within the scope of SEQ ID NO:210.

It would have been obvious to one of ordinary skill in the art to modify the peptide from Drmanac by adding an acetyl group to the N-terminus and an amide group to the C-terminus, thereby arriving at the invention of claim 1. The motivation to do so would be to protect the protein from degradation after administration as taught by Drmanac, thereby giving the protein a longer time to have its therapeutic effect.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with

this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 3, 5 – 6, and 14 – 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 16 and 14 – 17 of copending Application No. 11/405601. Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims recite the same polypeptides and compositions, although the '601 case also encompasses distinct products; see for example claim 1 of the '601 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker, Ph.D./
Patent Examiner, Art Unit 1649
June 9, 2008